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PRIMARY IRRITATION EVALUATION PROGRAM

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Edgewood Arsenal, Maryland

September 1972

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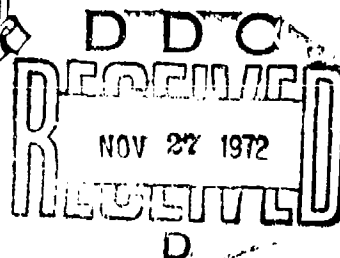
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PRIMARY IRRITATION EVALUATION PROGRAM
STUDY NUMBERS 51-001-73, 51-002-73, AND 51-003-73
SEPTEMBER 1972

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13. ABSTRACT Three candidate repellents were evaluated on New Zealand white rabbits for their potential to cause skin and eye irritation. The data obtained serve as a basis for making the following recommendations which are intended only for guidance in further entomological testing of the compounds. These recommendations do not constitute approval for testing on human volunteers. a. ENT-35237-Ga was found to be irritating to the skin of rabbits and should be resubmitted in the form and at the concentration of its intended use so that its irritation potential can be reexamined. b. ENT-35239-Ga is not expected to irritate human eyes if the compound should accidentally get into the eyes, provided it is washed out as soon as possible. There is no restriction for acute application to human skin. c. ENT-35240-Ga should be used with caution around the eyes and mucosa. The technical grade compound should be used only on human skin found by examination to have no abrasions or may be used as a clothing impregnant.			

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14. KEY WORDS	LINK A		LINK B		LINK C	
	ROLE	WT	ROLE	WT	ROLE	WT
Toxicity ENT-35237-Ga ENT-35239-Ga ENT-35240-Ga N,N-dipropyldodecanamide N-propyl-1-butanefulfonamide N-butyl-1-butanefulfonamide Primary irritation Eye irritation study Skin irritation study						
II						

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ABSTRACT

Three candidate repellents were evaluated on New Zealand white rabbits for their potential to cause skin and eye irritation. The data obtained serve as a basis for making the following recommendations which are intended only for guidance in further entomological testing of the compounds. These recommendations do not constitute approval for testing on human volunteers.

a. ENT-35237-Ga was found to be irritating to the skin of rabbits and should be resubmitted in the form and at the concentration of its intended use so that its irritation potential can be reexamined.

b. ENT-35239-Ga is not expected to irritate human eyes if the compound should accidentally get into the eyes, provided it is washed out as soon as possible. There is no restriction for acute application to human skin.

c. ENT-35240-Ga should be used with caution around the eyes and mucosa. The technical grade compound should be used only on human skin found by examination to have no abrasions or may be used as a clothing impregnant.

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SEPTEMBER 1972

1. REFERENCES.

a. Memorandum of Understanding between the Department of the Army, Office of The Surgeon General; Armed Forces Pest Control Board and the United States Department of Agriculture effective December 1970.

b. Letter, US Department of Agriculture, Gainesville, Florida, dated 21 June 1972, to this Agency.

c. Toxicology Division Procedural Guide, USAEHA, 1972.

2. PURPOSE. This report classifies the candidate repellents listed according to the categories described in the Appendix as determined by a study of their effects on the skin and eyes of rabbits. The information contained in this report is intended only for guidance in further entomological testing of the compounds and does not constitute approval for testing on human volunteers.

3. SUMMARY OF FINDINGS. The categories assigned to the test compounds are based upon their ability to cause primary irritation of the skin

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or eyes of New Zealand white rabbits. The following compounds are
classified according to the categories listed and defined in the Appendix:


Study No.	ENT No.	Physical State of Chemical Compound	PIEP Categories Skin Eyes	Compound Chemical Name or Other Identification Symbol
51-001-73	35237-Ga	Clear liquid	IV -	N,N-dipropyldodecanamide
51-002-73	35239-Ga	White, crystalline solid	I A	N-propyl-1-butanefulfon- amide
		Acetone solution of technical grade compound	I -	N-propyl-1-butanefulfon- amide
51-003-73	35240-Ga	Clear, crystalline solid	II C	N-butyl-1-butanefulfon- amide
		Acetone solution of technical grade compound	I -	N-butyl-1-butanefulfon- amide

4. RECOMMENDATIONS. Recommendations pertaining to each compound studied
can be found in the Appendix by referring to its primary irritation
evaluation program category. Those compounds found to be irritating to
the eyes should be resubmitted in the form and at the concentration of
their intended use so that their irritation potential can be reexamined.


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APPENDIX
PRIMARY IRRITATION EVALUATION PROGRAM
DEFINITIONS OF CATEGORIES OF COMPOUNDS BEING
CONSIDERED FOR ACUTE APPLICATIONS

CATEGORY I - (Formerly Categories I and II) - Compounds producing no primary irritation of the intact skin or no greater than mild primary irritation of the skin surrounding an abrasion. (INTERPRETATION: No restriction for acute application to the human skin).

Except when specifically requested for individual compounds, the following Eye Injury Categories A through F, are determined only for those compounds which are in Category I.

EYE CATEGORIES:

A. Compounds noninjurious to the eye. (INTERPRETATION: Irritation of human eyes is not expected if the compound should accidentally get into the eyes, provided it is washed out as soon as possible).

B. Compounds producing mild injury to the cornea. (INTERPRETATION: Should be used with caution around the eyes).

C. Compounds producing mild injury to the cornea and, in addition some injury to the conjunctiva. (INTERPRETATION: Should be used with caution around the eyes and mucosa).

D. Compounds producing moderate injury to the cornea. (INTERPRETATION: Should be used with extreme caution around the eyes).

E. Compounds producing moderate injury to the cornea and, in addition, producing some injury to the conjunctiva. (INTERPRETATION: Should be used with extreme caution around the eyes and mucosa).

F. Compounds producing severe injury to the cornea and to the conjunctiva. (INTERPRETATION: Should be used with extreme caution. It is recommended that use be restricted to areas other than the face).

CATEGORY II - (Formerly Category III) - Compounds producing mild primary irritation of the intact skin and the skin surrounding an abrasion. (INTERPRETATION: Should be used only on human skin found by examination to have no abrasions or may be used as a clothing impregnant. However, if the compound might come in contact with abraded skin, a prophetic patch test should be conducted on human skin to determine primary irritation potential).